REMARKS

Claims 1-5 are pending in the instant application. Claims 1, 4, and 5 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,057,655 ("Okada"). Applicants note that U.S. Patent No. 5,057,655, rather than Okada, is cited by Examiner in the Office Action. However, reference to the 5,057,655 patent was erroneous, such error being previously confirmed by Examiner. In addition, claims 2 and 3 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claims and any intervening claims.

In view of the following remarks/arguments, Applicants respectfully submit that this application is in complete condition for allowance and requests reconsideration of the application in this regard.

35 U.S.C. §102(b) – Rejection of Claims 1, 4, and 5

Examiner has rejected claims 1, 4, and 5 under 35 U.S.C. §102(b) as being anticipated by Okada. More specifically, in rejecting independent claim 1, Examiner relies on a lack of disclosure of chlorine content in the lactulose-containing powder compositions of Okada, such lack of disclosure in combination with a lack of caking, as observed in the first paragraph of column 11, is believed by Examiner to suggest a lactulose-containing powder composition including less than 0.08 parts by weight per 1 part by weight of protein. Applicants respectfully disagree.

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It is well established that "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). For the reasons set forth below, Okada clearly fails to teach each and every element of Applicants' invention as recited at least in independent claim 1 and, more specifically, Applicants respectfully submit that Okada at least fails to describe, either expressly or inherently, the method for producing a lactulose-containing powder composition of claim 1 which includes preparing a raw material liquid so that a chlorine content is no more than 0.08 parts by weight per 1 part by weight of protein.

As already indicated by Examiner, there is no specific or explicit teaching that the free-flowing lactulose-containing powders of Okada, in fact, include chlorine contents of no more than 0.08 parts by weight per 1 part by weight of protein. It is further noted that Okada appears to be directed towards utilizing calcium hydroxide for the isomerization reaction of lactose to adjust its pH to provide a process for preparing a free-flowing lactulose-containing powder for feed which is high in lactulose content and is not agglomerated and caked. Notably, while there is no disclosure, per se, of the chlorine content in the lactulose-containing powders of Okada, one skilled in the art would understand these powder compositions to include more than 0.08 parts by weight of chlorine per 1 part by weight of protein.

Hereinafter, Applicants will discuss the chlorine content in whey and, more specifically, the chlorine content of the whey of Okada for the purpose of clarifying that the

PAGE 9/24 * RCVD AT 1/4/2006 12:11:03 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-6/25 * DNIS:2738300 * CSID:513 241 6234 * DURATION (mm-ss):07-46

claimed invention, as recited in independent claim 1, is not taught by Okada. In so doing, Applicants emphasize that it is well known in the art that chlorine is contained in the ash content (salt content) of whey.

Accordingly, with specific reference to Table 3.3.4. of MILK AND DAIRY PRODUCTS IN HUMAN NUTRITION, 1983, pp.380-381, a copy of which is attached as Exhibit A, the average concentrations of certain constituents of whey and whey powder, including chlorine and protein, are shown, such whey being understood by one skilled in the art to be the raw material of the lactulose-containing powder compositions disclosed in Okada. From the values of the protein and chlorine contents listed next to the entries of "Protein" and "Cl" in this table, the chlorine content in whey, *i.e.* in the whey of Okada, can be calculated as 0.13 parts by weight per 1 part by weight of protein (this value is obtained by dividing 1.0 and 16 by 8 for whey and 125 for whey powder, respectively).

In view thereof, Applicants note that the protein content in TABLE 8, which shows the lactulose-containing powder composition, *i.e.*, an end product, of Example 1 of Okada, is almost the same as that in TABLE 7, which shows the raw material whey powder composition of the lactulose-containing powder. In addition, a comparison of TABLES 7 and 8 further illustrates that the ash content, which includes chlorine, is slightly increased from 7.5% (TABLE 7) to 9.3% (TABLE 8). From this data, it is readily apparent to one skilled in the art that the chlorine content of the lactulose-containing powder of Example 1 of Okada is 0.13 parts by weight or more per 1 part by weight of protein. Similarly, as discussed further below, since the

PAGE 10/24 * RCVD AT 1/4/2006 12:11:03 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-6/25 * DNIS:2738300 * CSID:513 241 6234 * DURATION (mm-ss):07-46

ash content, including the chlorine content, with respect to protein in Example 2 of Okada is higher than the lactulose-containing powder composition of Test 1 due to ultrafiltration, it leaves no doubt that the chlorine content of the lactulose-containing powder of Example 2 of Okada is 0.13 parts by weight or more per 1 part by weight of protein.

Notably, the ash content, including the chlorine, of the lactulose-containing powder compositions of Okada, as indicated above, is not reduced by the ultrafiltration of whey in Test 2 of Okada. This fact is further ascertained by comparing TABLE 1, which shows the composition of the filtered material of the whey in Example 2 of Okada, and a value obtained by converting the ash content listed in TABLE 7, which shows a typical whey powder composition to per solid content. More specifically, the ash content of the filtered material by ultrafiltration of the whey in Okada can be calculated as 0.5 / 5.2 x 100 = 9.6% since the content of ash is 0.5 with respect to a total solid content of 5.2 (with reference to TABLE 1). In contrast, the ash content of the typical whey prior to filtration can be calculated as 7.5 / 97.5 x 100 = 97.5 with reference to TABLE 7. Accordingly, the ash, including chlorine, is not reduced.

The fact that the ash in powder prepared in Example 2 of Okada is not reduced can also be acknowledged by simply comparing an ash content of 7.5% in TABLE 7, showing the typical whey powder composition, and an ash content of 9.6% in TABLE 14, showing the powder composition of Test 2, since the water contents listed in the two tables are almost equal.

As generally already indicated, Okada discloses the use of a permeate obtained by ultrafiltration in which the ash content, including chlorine, is generally increased with respect to

PAGE 11/24 * RCVD AT 1/4/2006 12:11:03 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-6/25 * DNIS:2738300 * CSID:513 241 6234 * DURATION (mm-ss):07-46

protein. In further support thereof, please see TABLE 1.1 and Figure 1.2 of ULTRA-FILTRATION and MICROFILTRATION HANDBOOK, 1998, pp.3-4, a copy of which is attached as Exhibit B, which discloses increases in ash content, including the chlorine content, with respect to protein in a permeate obtained by ultrafiltration. More specifically, as is understood by one skilled in the art, after ultrafiltration, substances having larger molecular weights, such as proteins, remain in the retente whereas substances having smaller molecular weights, such as monovalent salts containing chlorine, migrate to the permeate. Accordingly, since the protein concentration in the permeate decreases, the ash content (salt content), including the chlorine content, with respect to protein is relatively increased even when the chlorine content in the permeate is not altered from the chlorine content in whey. The fact that the ash content (salt content), including the chlorine content, with respect to protein is increased can also be acknowledged by simply comparing an ash content of 7.5% and a protein content of 13.0% in TABLE 7, showing the typical whey powder composition, and an ash content of 9.6% and a calculated protein content of 10.625% in TABLE 14, showing the powder composition of Test 2.

In view of the above, Applicants submit that the chlorine content of the lactulose-containing powder manufactured using the methods taught in Okada, as would be understood by one skilled in the art, is higher than the chlorine content of the whey used therein, namely, higher than 0.13 parts by weight per 1 part by weight of protein. In stark contrast, the chlorine content of the lactulose-containing powder composition, as recited in Applicants' claim 1 of the present invention, is no more than 0.08 parts by weight per 1 part by weight of protein. Therefore, in

PAGE 12/24 * RCVD AT 1/4/2006 12:11:03 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-6/25 * DNIS:2738300 * CSID:513 241 6234 * DURATION (mm-ss):07-46

terms of at least the chlorine content, the subject matter of claim 1 is patentably distinct, and thus not anticipated, by the lactulose-containing powder of Okada.

Furthermore, Examiner asserts that the lack of caking observed in the first paragraph of column 11 suggests that less than 0.08 parts/part protein must be present in the lactulose-containing powder compositions of Okada. Applicants respectfully disagree.

The lack of caking observed in Okada merely illustrates that the use of calcium hydroxide for the isomerization reaction of lactose to adjust its pH can provide a process for preparing a free-flowing lactulose-containing powder for feed that is not agglomerated and caked. Accordingly, the lack of caking does not suggest to one skilled in the art that less than 0.08 parts/part protein is present in the lactulose-containing powder compositions of Okada but rather illustrates the advantages of using calcium hydroxide.

Additionally, as disclosed in lines 1 to 6, column 11 of Okada, the test to evaluate the lack of caking was conducted in sealed conditions in which moisture absorption would not occur. In contrast, as disclosed in Example 1 of Applicants' specification (lines 14 to 18, page 29), the lactulose-containing powder composition of the present invention was left to stand in an environment of 81% relative humidity. That is, Test Example 2 of the present invention proved that samples B-2 to B-4 and Samples B-6 to B-9 retained good flowability and displayed a favorable state compared to Samples B-1 and B-5, which correspond to the lactulose-containing powder of Okada. The result of Test Example 1 of the present invention shows that the stability to humidity is lost when the chlorine content is more than 0.08 parts by weight. Since the tests in

PAGE 13/24 * RCVD AT 1/4/2006 12:11:03 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-6/25 * DNIS:2738300 * CSID:513 241 6234 * DURATION (mm-ss):07-46

Okada, which include merely a sealed condition in which moisture absorption cannot occur, are used to illustrate the effects of calcium hydroxide and do not involve other testing, such as testing in an environment of 81% relative humidity, there simply is no suggestion by the lack of caking that the lactulose-containing powder compositions disclosed therein include less than 0.08 parts/part protein.

Accordingly, Applicants respectfully submit that Okada fails to teach, *i.e.*, to describe, either expressly or inherently, Applicants' method for producing a lactulose-containing powder composition of claim 1 which includes preparing a raw material liquid so that a chlorine content is no more than 0.08 parts by weight per 1 part by weight of protein. Therefore, the rejection of at least claim 1 under 35 U.S.C. 102(b) is overcome.

Information Disclosure Statement

Applicants further kindly request that the Examiner initial the Okada *et. al.* reference (USPN 4057655), the JP 2741812 reference, and the JP 54-15829 reference that are listed on the Information Disclosure Statement that was received by the Patent Office on November 30, 2004.

CONCLUSION

In view of the foregoing response, this application is submitted to be in complete condition for allowance and early notice to this affect is earnestly solicited. If there is any issue

PAGE 14/24 * RCVD AT 1/4/2006 12:11:03 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-6/25 * DNIS:2738300 * CSID:513 241 6234 * DURATION (mm-ss):07-46

that remains which may be resolved by telephone conference, the Examiner is invited to contact the undersigned in order to resolve the same and expedite the allowance of this application.

Applicants do not believe that this response requires that any fees be submitted, however, if any fees are deemed necessary, these may be charged to Deposit Account No. 23-3000.

Respectfully submitted,

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PAGE 15/24 * RCVD AT 1/4/2006 12:11:03 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-6/25 * DNIS:2738300 * CSID:513 241 6234 * DURATION (mm-ss):07-46

JAN-04-2006 11:04 513 241 6234 P.16

MILK AND DAIRY PRODUCTS IN HUMAN NUTRITION

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Federal Republic of Germany

51 figures and 49 tables

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513 241 6234

Exhibit A

PAGE 16/24 * RCVD AT 1/4/2006 12:11:03 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-6/25 * DNIS:2738300 * CSID:513 241 6234 * DURATION (mm-ss):07-46

PAGE 17/24 * RCVD AT 1/4/2006 12:11:03 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-6/25 * DNIS:2738300 * CSID:513 241 6234 * DURATION (mm-ss):07-46

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Contents

JAN-04-2006 11:04 513 241 6234 513 241 6234 P.17

PAGE 18/24 * RCVD AT 1/4/2006 12:11:03 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-6/25 * DNIS:2738300 * CSID:513 241 6234 * DURATION (mm-ss):07-46

JAN-04-2006 11:04 513 241 6234 P.18

PAGE 19/24 * RCVD AT 1/4/2006 12:11:03 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-6/25 * DNIS:2738300 * CSID:513 241 6234 * DURATION (mm-ss):07-46
JAN-04-2006 11:05 513 241 6234 P.19
513 241 6234

PAGE 20/24 * RCVD AT 1/4/2006 12:11:03 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-6/25 * DNIS:2738300 * CSID:513 241 6234 * DURATION (mm-ss):07-46

JAN-04-2006 11:05 513 241 6234 P.20

Table 3.3.4: Average concentrations of some constituents of whey and whey powder (in the case of two figures: first figure refers to sweet whey, second figure to acid whey)

Constituent	Units	Content of whey per l	Content of whey powder per kg
Dry matter	g	61	
Moisture	g		44
Lactose	g	48/42	740/660
Protein	g	8	125
Fat	g	2	10
Minerals	g	5/7	80/105
Lactic acid	g	1/5	2/ 42
Ca	g	0.5/1.0	7/ 20
P	g	0.5	8
K	g	1.4	20
Na	g	0.45	9
Cl	g	1.0	16
Mg	g	0.04/0.08	1/2
Zn	mg	0.3 /2.3	10/60
Fe	mg	0.9	
Cu	mg	0.2	3
Mn	µg	6/26	120/470
Thiamine	mg	0.4	5
Riboflavin	mg	1.4	25
Pyridoxine	mg	0.5	
Cobalamin	µg	1.5	25
Nicotinic acid	mg	2	8
Folic acid	µg	50	220
Pantothenic acid	mg		115
Ascorbic acid	mg	9	45
pH value		6.0/4.5	

References: *Adrian 1977, Adrian & Bourlier 1980, Alais 1981, Antila et al. 1982, Bednarski et al. 1978, Blanc 1974, Capella et al. 1974, Cerbulis & Farrell 1975, Cremer et al. 1980/81, Dalum 1976, Delaney 1976, Delaney & O'Sullivan 1973, Delaveau & Jelen 1979, Empie & Melachouris 1978, Giroux et al. 1975, Glass & Hedrick 1977a & b, Halden 1978, Hickey et al. 1980, Jelen 1978, 1979a & b, Jensen & Hansen 1978, Jönsson 1974, Josephson et al. 1974 & 1975, Kosikowski 1978 & 1979b, Kube et al. 1977, Lenoir 1981, Mavropoulou & Kosikowski 1973, Mirabel & Goudal*

1981, Nemitz 1977a & b, Nickerson 1978, Porter 1975, Preller & Röhrig 1978, Racotta et al. 1978, Reimerdes 1981, Rückemann et al. 1973, Smith 1976, Shulkamy 1976, Tamime & Deeth 1980, Wagner 1980, Wagner et al. 1975, Weihrauch & Schwartz 1974, Wong et al. 1978b, Wyeth 1972.

– A variety of whey-based drinks with fruit flavours or a large number of other flavours are on the market. The production of a whey-soya milk as well as a whey-ground nut one has been suggested particularly for child feeding. In addition, several fermented whey drinks have been produced.
– The idea has been put forward that a fresh product resembling quarg could be made from whey.
– The composition of whey makes it a suitable nutrient medium for the production of yeast protein.
(Aguilera & Kosikowski 1978, Allum 1980, Baumgärtel 1964, Blackburn & Bassette 1982, Cuddy & Zall 1982, Dellamonica et al. 1979, Funck 1948, Hanna et al. 1978, Herrmann et al. 1980, Holsinger et al. 1974, 1977, 1978a & b, Kapoor & Gupta 1978, Karlin & Gaudin-Harding 1970, Kosikowski 1967, 1968 & 1981, Kriel & van Tonder 1979, Lang & Lang 1976 & 1979, Lutskova 1966, Mair-Waldburg 1955, Mann 1977, Mathur & Shahani 1979, Pedziwilk et al. 1970, Satterlee 1975, Sienkiewicz & Riedel 1975, Stull et al. 1977, Surazynski et al. 1968, Vitti 1981, Wagner 1980, Weisberg & Goldsmith 1969, Wingerd et al. 1970, Zollikofer 1974).

3.3.8.2. Milk protein products

Because the lactose content of whey is very high modern technology is used to separate the whey proteins in as concentrated a form as possible. The same methods are used to obtain the proteins from milk. The following milk protein products have been obtained: rennet and acid casein, caseinates, co-precipitates, heat precipitated whey proteins, whey protein or milk protein concentrates obtained by ultrafiltration. Also small quantities of textured milk proteins for a number of food applications have already been produced. Milk and whey protein concentrates can also be obtained by gel filtration *(Hynd 1975, Jonas 1973, Meggle 1979, van der Merwe & Downes 1981, Müller & Kabus 1979, Ozimek et al. 1980, Richert 1975).*

Average values for the composition of caseinates and co-precipitates are given in Table 3.3.5. The PER value of caseinates is higher than that of casein. Co-precipitates are obtained by precipitating together casein and whey proteins. 96 % of the milk proteins and about 70 % of the whey proteins are removed from the milk in this way. Co-precipitates have the same amino acid composition and biological value as the total milk protein. They are richer in sulphur-containing amino acids than the caseinates. When calcium chloride is used for precipitation, products with a relatively high Ca

JAN-04-2006 11:06 513 241 6234 P.21

ULTRAFILTRATION *and* MICROFILTRATION HANDBOOK

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PAGE 21/24 * RCVD AT 1/4/2006 12:11:03 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-6/25 * DNIS:2738300 * CSID:513 241 6234 * DURATION (mm-ss):07-46

PAGE 22/24 * RCVD AT 1/4/2006 12:11:03 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-6/25 * DNIS:2738300 * CSID:513 241 6234 * DURATION (mm-ss):07-46

JAN-04-2006 11:06 513 241 6234 513 241 6234 P.22

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TABLE OF CONTENTS

Table 1.1. Characteristics of membrane processes.

Process	Driving Force	Retentate	Permeate
Osmosis	Chemical potential	Solutes, water	Water
Dialysis	Concentration difference	Large molecules, water	Small molecules, water
Microfiltration	Pressure	Suspended particles, water	Dissolved solutes, water
Ultrafiltration	Pressure	Large molecules, water	Small molecules, water
Nanofiltration	Pressure	Small molecules, divalent salts, dissociated acids, water	Monovalent ions, undissociated acids, water
Reverse osmosis	Pressure	All solutes, water	Water
Electrodialysis	Voltage/current	Nonionic solutes, water	Ionized solutes, water
Pervaporation	Pressure	Nonvolatile molecules, water	Volatile small molecules, water

Figure 1.1 shows a classification of various separation processes based on particle or molecular size and the primary factor affecting the separation process. The major membrane separation processes—reverse osmosis (RO), nanofiltration (NF), ultrafiltration (UF), microfiltration (MF), dialysis, electrodialysis (ED), and pervaporation (PV)—cover a wide range of particle/molecular sizes and applications. Among membrane separation processes, the distinction between the various processes is somewhat arbitrary and has evolved with usage and convention. Table 1.1 shows the characteristics of various membrane processes. Osmosis (to be discussed in detail in Section 1.C.) is the transport of solvent through a semipermeable membrane from the dilute solution side to the concentrated solution side of the membrane. It is driven by chemical potential differences between the water on either side of the membrane. With an ideal semipermeable membrane, only water should permeate through the membrane. The common laboratory technique of dialysis, on the other hand, is primarily a technique for purifying macromolecules, such as desalting of proteins, and the primary driving force is the difference in concentration of the permeable species between the solution in the dialysis bag and outside the bag. Electrodialysis relies primarily on voltage or electromotive force and ion-selective membranes to effect a separation between charged ionic species.

What distinguishes the more common pressure-driven membrane processes—microfiltration, ultrafiltration, nanofiltration, and reverse osmosis—is the application of hydraulic pressure to speed up the transport process. However, the nature of the membrane itself controls which components permeate and which

Figure 1.1. Useful ranges of various separation processes.

PAGE 24/24 * RCVD AT 1/4/2006 12:11:03 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-6/25 * DNIS:2738300 * CSID:513 241 6234 * DURATION (mm-ss):07-46

JAN-04-2006 11:07 513 241 6234 P.24

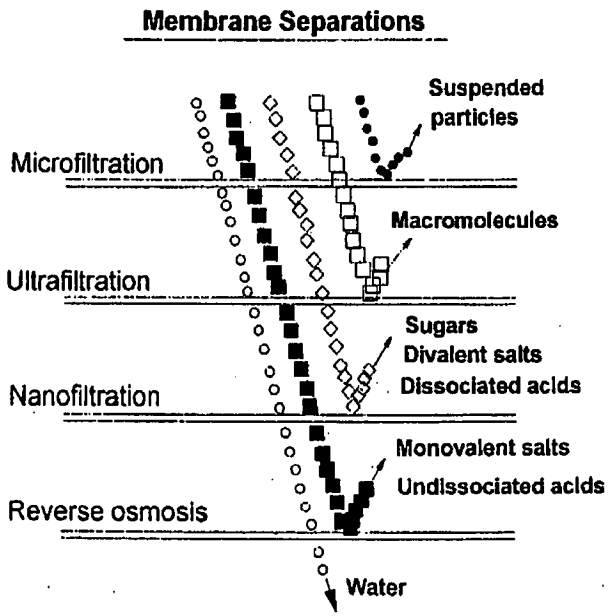

Figure 1.2. Pressure-driven membrane processes and their separation characteristics.

are retained, as shown in Figure 1.2. In its ideal definition, reverse osmosis retains *all* components other than the solvent (e.g., water) itself, while ultrafiltration retains only macromolecules or particles larger than about 10–200 Å (about 0.001–0.02 μm). Microfiltration, on the other hand, is designed to retain particles in the "micron" range, that is, suspended particles in the range of 0.10 μm to about 5 μm (particles larger than 5–10 μm are better separated using conventional cake filtration methods). Thus, in its broadest sense, reverse osmosis is essentially considered to be a dewatering technique, while ultrafiltration can be looked at as a method for simultaneously purifying, concentrating, and fractionating macromolecules or fine colloidal suspensions. Microfiltration is used mainly as a clarification technique, separating suspended particles from dissolved substances, provided the particles meet the size requirements for microfiltration membranes.

Nanofiltration is a relatively new process that uses charged membranes with pores that are larger than RO membranes, but too small to allow permeation of many organic compounds such as sugars. They also have a useful property in

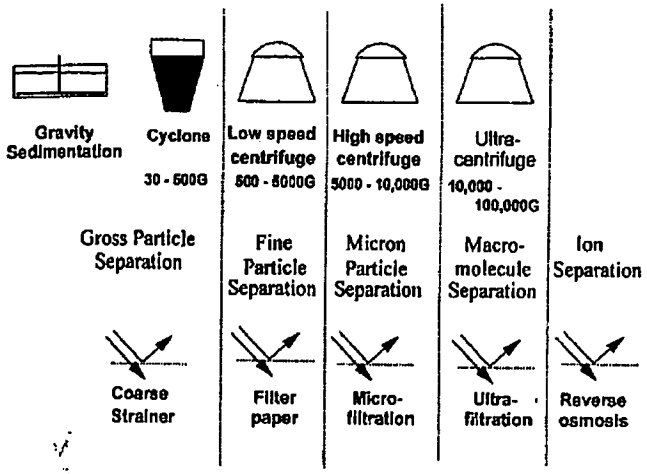

Figure 1.3. Comparison of centrifugation and filtration processes.

that they can separate dissociated forms of a compound from the undissociated form; e.g., organic acids such as lactic, citric, and acetic pass through easily at low pH but are rejected at higher pH when in their salt forms (Raman et al. 1994).

In terms of versatility, centrifugation is perhaps the only method to match membrane technology (Figure 1.3). However, an absolute requirement for centrifugal processes is the existence of a suitable density difference between the two phases that are to be separated, in addition to the two phases being immiscible. Membrane separation processes have no such requirement; indeed, the real value of membranes is that they permit separation of dissolved molecules down to the ionic range, provided the appropriate membrane is used.

Figure 1.4 shows some typical examples of components that fall under these four processes. Membranes are usually classified according to the size of the separated components, and thus particle sizes in MF applications are specified in microns (i.e., μm). However, with UF membranes, it is customary to refer to the "molecular weight cut-off" (MWCO) instead of particle size per se. In the early days of membrane technology, UF membranes were characterized by studying the relative permeabilities of proteins and polyethylene glycols, which were characterized in terms of their molecular weights. Even though it is known that molecular weight alone does not determine the size of a protein and, indeed, many manufacturers use dextrans rather than proteins to characterize UF membranes (as discussed in Chapter 3), this terminology is still used, sometimes prefixed with the word *nominal*, as in NMWCO. Thus, UF covers "particles"

513 241 6234 P.24

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